§ 703.8 Prohibited fees.

(a) A federal credit union's officials, senior management employees, and immediate family members of such individuals, may not receive pecuniary consideration in connection with the making of an investment by the federal credit union. The prohibition contained in this subsection also applies to any employee not otherwise covered if the employee is directly involved in investments or deposits unless the board of directors determines that the employee's involvement does not present a conflict of interest.

(b) All transactions with business associates or family members not specifically prohibited by paragraph (a) of this section must be conducted at arm's length and in the interest of the credit union.

§ 703.9 Grandfather provisions.

(a) Subject to safety and soundness considerations, a federal credit union's authority to hold an investment is governed by the regulations in effect at the time of purchase. Past regulations governing certain investments are described in paragraphs (b) through (d) of this section.

(b) Subject to safety and soundness considerations, a federal credit union may hold a fixed-rate CMO/REMIC purchased:

(1) Before December 2, 1991;

(2) On or after December 2, 1991, but before July 30, 1993, if its average life does not extend or shorten by more than 6 years if interest rates rise or fall 300 basis points; or

(3) On or after December 2, 1991, but before the effective date of the final regulation, if for the purpose of reducing interest rate risk.

(c) Subject to safety and soundness considerations, a federal credit union may hold a variable-rate CMO/REMIC purchased:

(1) Before December 2, 1991;

(2) On or after December 2, 1991, but before July 30, 1993, if:

(i) The interest rate is reset at least annually;

(ii) The maximum allowable interest rate on the instrument is at least 300 basis points above the interest rate of the instrument at the time of purchase; and

(iii) The interest rate of the instrument varies directly (not inversely) with the index upon which it is based and is not reset as a multiple of the change in the related index; or

(3) On or after July 30, 1993, but before the effective date of this regulation, if:

(i) The interest rate is reset at least annually;

(ii) The maximum allowable interest rate on the instrument is at least 300 basis points above the interest rate of the instrument at the time of purchase; and

(iii) The interest rate of the instrument varies directly (not inversely) with the index upon which it is based and is not reset as a multiple of the change in the related index; and

(iv) The estimated change in its price is 17 percent or less, due to an immediate and sustained parallel shift in the yield curve of plus or minus 300 basis points.

(d) Subject to safety and soundness considerations, a federal credit union may hold a CMO/REMIC residual, SMBS, or zero coupon security with a maturity greater than 10 years, if the investment was purchased:

(1) Before December 2, 1991; or

(2) On or after December 2, 1991, but before the effective date of the final regulation, if for the purpose of reducing interest rate risk.

(e) All grandfathered investments are subject to the reporting and risk management requirements of § 703.3.

[FR Doc. 95–28705 Filed 11–28–95; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

21 CFR Part 872

[Docket No. 95N–0298]

Dental Devices; Effective Date of Requirement for Premarket Approval of Partially Fabricated Denture Kits

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for partially fabricated denture kits. The agency is also summarizing its proposed findings regarding the benefits to the public from use of the device as well as the degree of risk of illness or injury intended to be eliminated or reduced by requiring that the device have an approved PMA or a completed PDP. In addition, FDA is announcing an opportunity for interested persons to request the agency to change the classification of the device based on new information.

DATES: Written comments by February 27, 1996; requests for a change in classification by December 14, 1995. FDA intends that if a final rule based on this proposal is issued, PMA's or notices of completion of PDP's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Louis Hlavinka, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to the devices that were on the market on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or notice of completion of a PDP until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) requirements (part 812 (21 CFR part 812)) until the date stipulated by FDA in the final rule requiring the submission of a PMA application or a notice of completion of a PDP for that device. At that time, an IDE must be submitted only if a PMA has not been submitted or a PDP not completed.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval

shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated, within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA or notice of completion of a PDP has been filed and may determine that such a request is appropriate for partially fabricated denture kits.

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House report (H. Rept.) on the amendments states that ''the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval.'' (H. Rept. 94–853 Cong., 2d sess. 42 (1976)).

A. Classification of Partially Fabricated Denture Kits

In the Federal Register of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying partially fabricated denture repair kits into class III. The preamble to the proposal to classify the device published in the Federal Register of December 30, 1980 (45 FR 85962), included the recommendation of the Dental Devices Classification Panel (the Panel), an FDA advisory committee, regarding the classification of the devices. The Panel recommended that partially fabricated denture kits be in class III (premarket approval). The Panel believed that general controls and performance standards would not provide reasonable assurance of the safety and effectiveness of these devices and that there was insufficient information to establish such standards.

In the Federal Register of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval for 31 class III preamendments devices. Among other items, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. Partially fabricated denture kits were not included in the list of devices identified in that notice. FDA updated its priorities in a preamendments class III strategy document made public through a Federal Register notice of availability published on May 6, 1994 (59 FR 23731). Accordingly, FDA has recently determined that partially fabricated denture kits identified in 21 CFR 872.3600 have a high priority for initiating a proceeding to require premarket approval because the safety and effectiveness of the device has not been established by valid scientific evidence as defined in § 860.7 (21 CFR 860.7). Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the partially fabricated denture kit have an approved PMA or declared completed PDP.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the partially fabricated denture kit within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the partially fabricated denture kit during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period of a PMA beyond 180 days unless the agency finds that ''* * * the continued availability of the device is necessary for the public health.''

FDA intends that, under § 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any partially fabricated denture kit which is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which a PMA approval has been denied or withdrawn.

If a PMA or a notice of completion of a PDP for the partially fabricated denture kit is not filed with FDA within 90 days after the date of issuance of any final rule requiring premarket approval for the devices, commercial distribution

of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that, for manufacturers not planning to submit a PMA immediately, an IDE application should be submitted to FDA at least 30 days before the end of the 90 day period after the final rule is published in the Federal Register to minimize the possibility of interrupting all availability of the device. FDA does not consider an investigation of the partially fabricated denture kit to pose a significant risk as defined in the IDE regulation. The device may be distributed for investigational use if manufacturers, importers, or other sponsors comply with the abbreviated requirements (§ 812.1(b)) of the IDE regulation.

C. Description of Device

A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring partially fabricated denture kits to have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

E. Risk Factors

Partially fabricated denture kits have been associated with potential risks relative to jaw relationships, adverse tissue reaction, and materials composition.

The risks associated with jaw relationships are: (1) Inaccurate vertical dimension of occlusion; (2) improper occlusal plane and tooth ridge relationships; (3) jaw joint dysfunction and esthetic problems caused by inaccurate reproduction of the physiologic dimensions of the mandible; and (4) unsatisfactory centric and eccentric relations to ensure proper distribution of pressure to the edentulous-bearing areas.

The risks related to adverse tissue reaction include: (1) Irritation of the oral cavity soft tissues; (2) monilial infection; (3) unusual hard and soft tissue changes; (4) tissue health maintenance difficulties; and (5) allergy or sensitization caused by the leaching of unreacted resin monomer on initial fitting or insertion of the denture.

The risks relative to materials composition: (1) Deterioration of the acrylic plastic denture base over time; (2) unsatisfactory performance of the denture materials; and (3) ill-fitting dentures resulting from decomposition or distortion of the acrylic plastic caused by improper finishing techniques and jeopardy to the patient's oral health resulting from the use of dentures fabricated by dental office techniques that bypass traditionally controlled, accepted, and proven laboratory procedures (Refs. 1 through 10).

F. Benefits of the Device

A partially fabricated denture kit is constructed by chemically bonding preformed teeth to a common base. The patient's mouth is used as a mold by partially polymerizing the resin denture base while the materials are in contact with oral tissues. The potential benefits intended from the use of a partially fabricated denture kit are: potential modification of the size and shape of the prefabricated denture to the specific oral configuration and relationships for some patients; a reduction in the amount of time needed by the practitioner and auxiliary staff to fabricate a denture for the patient; fewer laboratory procedures compared with conventional methods of denture construction outside the dental office; reduction of commercial laboratory charges and potential reduction of denture costs to the patient; and availability of a denture intended for temporary use. (Refs. 1, 3 through 5, 8, and 10).

G. Need for Information for Risk/Benefit Assessment of the Device

FDA classified the partially fabricated denture kit into class III because it determined that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has determined that the special controls that may now be applied to class II devices under the Safe Medical Devices Act of 1990 also would not provide such assurance. FDA has weighed the probable risks and benefits to the public health from the use of the device and believes that the literature reports and other information discussed above suggest the potential for unreasonable risks associated with the use of the device. These risks must be addressed by the manufacturers of partially fabricated denture kits. FDA believes that partially fabricated denture kits should undergo premarket approval to establish effectiveness and to determine whether the benefits to the patient are sufficient to outweigh any risk.

II. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the act and § 814.20 (21 CFR 814.20) of the procedural regulations for PMA's. Such a PMA should include a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known to the applicant that have not been identified in this document; (2) the effectiveness of the specific partially fabricated denture kit that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence as defined in § 860.7 and should be obtained from well-controlled clinical studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the partially fabricated denture kit for its intended use. In addition to the basic requirements described in § 814.20(b)(6)(ii) for a PMA, it is recommended that such studies employ a protocol that meets the criteria described below.

Applicants should submit any PMA in accordance with FDA's guideline entitled ''Guideline for the Arrangement and Content of a PMA Application.'' The guideline is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850.

A. General Protocol Requirements

The partially fabricated denture kit should be evaluated in a prospective, randomized, controlled clinical trial that uses adequate controls. The study must attempt to answer all of the general and specific questions about the safety and effectiveness of the devices, including the risk to benefit ratio. These questions should relate to the pathophysiologic effects which the

device produces, as well as the primary and secondary variables analyzed to evaluate safety and effectiveness. Study endpoints and study success must be defined.

Animal toxicity studies should be conducted according to the International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part-1: Evaluation and Testing.'' Specifically:

(1) The selection of material(s) to be used in device manufacture and its toxicological evaluation should initially take into account full characterization of the material, for example, formulation, known and suspected impurities, and processing.

(2) The material(s) of manufacture, the final product and possible leachable chemicals or degradation products should be considered for their relevance to the overall toxicological evaluation of the device.

(3) Any in vitro or in vivo experiments or tests must be conducted according to recognized good laboratory practices followed by an evaluation by competent informed persons.

(4) Any change in chemical composition, manufacturing process, physical configuration or intended use of the device must be evaluated with respect to possible changes in toxicological effects and the need for additional testing.

(5) The toxicological evaluation performed in accordance with the guidance should be considered in conjunction with other information from other nonclinical studies and postmarket experiences for an overall safety assessment.

Examples of questions to be addressed by the clinical studies may include the following:

1. What morbidity (irritation of the oral cavity soft tissues, monilial infection, unusual hard and soft tissue changes, sensitization, or allergic response) is associated with the subject device in the patient population and how does this compare to the control?

2. What impact does the device have on the vertical dimension of the occlusion?

3. What are the long term effects of the device on the oral tissue?

4. What changes in physical characteristics (hardness, dimensional stability, etc.) of the materials take place over time?

5. Does the device provide a functional level of retention for the user?

6. Does the device allow sufficient comfort for the user?

7. Does the partially fabricated denture provide adequate strength for the denture to function properly?

8. What criteria are used to select the correct size of partially fabricated denture for an individual patient?

9. Because the teeth are preset, how is the individual occlusal plane determined to avoid traumatic occlusion?

10. Does the device allow the patient to be able to masticate food, insofar as oral and psychologic conditions will permit?

11. Does use of the device result in the patient presenting a normal individual appearance that satisfies esthetic requirements?

Statistically valid investigations should include a clear statement of the objectives of the study. Appropriate rationale, supported by background literature on previous uses of the device and proposed mechanisms for its effect, should be presented as justification for the questions to be answered, and the definitions of study endpoints and success. Clear study hypotheses should be formulated based on this information.

B. Study Sample Requirements

The subject population should be well defined. Ideally, the study population should be as homogeneous as possible in order to minimize selection bias and reduce variability. Otherwise, an unusually large population may be necessary to achieve statistical significance. Independent studies producing comparable results at multiple study sites using identical protocols are necessary to demonstrate repeatability. Justification must be provided for the sample size used to show that a sufficient number of completely edentulous patients were enrolled to attain statistically and clinically meaningful results. Eligibility criteria for the subject population should include the subject's potential for benefit, the ability to detect a benefit in the subject, the absence of both contraindications and any competing risk and assurance of subject compliance. In a heterogeneous sample, stratification of the patient groups participating in the clinical study may be necessary to analyze homogeneous subgroups and thereby minimize potential bias. All endpoint variables should be identified, and a sufficient number of patients from each subgroup analysis should be included to allow for stratification by pertinent demographic characteristics.

The investigation should include an evaluation of comparability between treatment groups and control groups (including historical controls). Baseline (e.g., age, gender, etc.) and other variables should be measured and compared between the treatment and control groups. The baseline variables should be measured at the time of treatment assignment, not during the course of the study. Other variables should be measured during the study as needed to completely characterize the device's safety and effectiveness.

C. Study Design

All potential sources of error, including selection bias, information bias, misclassification bias, comparison bias, or other potential bias should be evaluated and minimized. The study should clearly measure any possible placebo effect. Treatment effects should be based on objective measurements. The validity of these measurement scales should be shown to ensure that the treatment effect being measured reflects the intended uses of the device.

Adherence to the protocol by subjects, investigators, and all other individuals involved is essential and requires monitoring to assure compliance by both patients and physicians. Subject exclusion due to dropout or loss to followup greater than 20 percent may invalidate the study due to bias potential; therefore, initial patient screening and compliance of the final subject population will be needed to minimize the dropout rate. All dropout must be accounted for and the circumstances and procedures used to ensure patient compliance must be well documented.

Endpoint assessment cannot be based solely on a statistical value. Instead, the clinical outcome must be carefully defined to distinguish between the evaluation of the proper function of the device versus its benefit to the subject. Statistical significance and effectiveness of the device must be demonstrated by the statistical results. However, under certain restricted circumstances, a clinically significant result may be acceptable without statistical significance.

Observation of all potential adverse effects must be recorded and monitored throughout the study and the followup period. All adverse effects must be documented and evaluated.

D. Statistical Analysis Plan

The involvement of a biostatistician is recommended to provide proper guidance in the planning, design, conduct, and analysis of a clinical study. There must be sufficient documentation of the statistical analysis and results including comparison group selection, sample size justification,

stated hypothesis test(s), population demographics, study site pooling justification, description of statistical tests applied, clear presentation of data and a clear discussion of the statistical results, and conclusions.

In addition to this generalized guidance, the investigator or sponsor is expected to incorporate additional requirements necessary for a well-controlled scientific study. These additional requirements are dependent on what the investigator or sponsor intends to measure or what the expected treatment effect is based on each device's intended use.

E. Clinical Analysis

The analysis which results from the study should include a complete description of all the statistical procedures employed, including assumption verification, pooling justification, population selection, statistical model selection, etc. If any procedures are uncommon or derived by the investigator or sponsor for the specific analysis, an adequate description must be provided of the procedure for FDA to assess its utility and adequacy. Data analysis and interpretations from the clinical investigation should relate to the medical claims.

F. Monitoring

Rigorous monitoring is required to assure that the study procedures are followed and that data are collected in accordance with the study protocol. Forceful monitors, who have appropriate credentials and who are not aligned with patient management or otherwise biased, contribute prominently to a successful study.

III. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the partially fabricated denture kit is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by December 14, 1995.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the partially fabricated denture kit is submitted, the agency will, by January 29, 1996, after consultation with the appropriate FDA advisory committee and by an order published in the Federal Register, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ad Hoc Committee for the Delivery of Quality Prosthetic Care for the Financially Disadvantaged, ''Final Report from the Ad Hoc Committee for the Delivery of Quality Prosthetic Care for the Financially Disadvantaged,'' *Journal of the American Dental Association*, 95:1026–1037, November 1977.

2. Chasens, A. I., ''Controversies in Occlusion,'' Dental Clinics of North America, 34:1:111–123, January 1990.

3. Council on Dental Materials and Devices, ''Association Reports: Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 98(2):268, February 1979.

4. Council on Dental Materials and Devices, ''Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 93(2):380, August 1976.

5. Council on Dental Materials and Devices, ''Reports of Councils and Bureaus: Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 90(3):669, March 1975.

6. Craig, R. G. et al., ''Dental Materials Properties and Manipulation,'' pp. 271–281, 5th ed., Mosby, St. Louis, MO, 1991.

7. Muzyka, B. C., and M. Glick, ''A Review of Oral Fungal Infections and Appropriate Therapy,'' *Journal of the American Dental Association*, 126:63–72, January 1995.

8. Phillips, R. W., ''Elements of Dental Materials For Dental Hygienists and Assistants,'' 3d ed., W. B. Saunders Co., 1977, pp. 130–138.

9. Shay, K., ''Identifying the Needs of the Elderly Dental Patient: The Geriatric Dental Assessment,'' Dental Clinics of North America, 38:3:499, 505–507, July 1994.

10. Vining, R. V., ''Council Comments on Prefabricated Dentures,'' a Letter to the Editor, *Journal of the American Dental Association*, 95:21, July 1977.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this device has been classified into class III since August 12, 1987, and manufacturers of this device legally in commercial distribution before May 28, 1976, or found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may, on or before February 27, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before December 14, 1995, submit to the Dockets Management Branch a written request to change the classification of the partially fabricated denture kit. Two copies of any request are to be submitted, except that individuals may submit one copy. Comments or requests

are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 872.3600 is amended by revising paragraph (c) to read as follows:

§ 872.3600 Partially fabricated denture kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any partially fabricated denture kit that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to a partially fabricated denture kit that was in commercial distribution before May 28, 1976. Any other partially fabricated denture kit shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: October 5, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95–29083 Filed 11–28–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

RIN 1018–AD44

Addition of Great Bay National Wildlife Refuge to the List of Open Areas for Hunting in New Hampshire

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to add Great Bay National Wildlife Refuge to the list of areas open for migratory game bird hunting and big game hunting in New Hampshire along with pertinent refuge-specific regulations for such activities. The Service has determined that such use will be compatible with the purposes for which the refuge was established. The Service has further determined that this action is in accordance with the provisions of all applicable laws, is consistent with principles of sound wildlife management, and is otherwise in the public interest by providing additional recreational opportunities of a renewable natural resource.

DATES: Comments may be submitted on or before January 29, 1996.

ADDRESSES: Assistant Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1849 C Street, NW, MS 670 ARLSQ, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Stephen R. Vehrs, at the address above; Telephone: 703–358–2029 X–5242.

SUPPLEMENTARY INFORMATION: National wildlife refuges are generally closed to hunting and sport fishing until opened by rulemaking. The Secretary of the Interior (Secretary) may open refuge areas to hunting and/or fishing upon a determination that such uses are compatible with the purpose(s) for which the refuge was established. The action must also be in accordance with provisions of all laws applicable to the areas, must be consistent with the principles of sound wildlife management, and must otherwise be in the public interest. This rulemaking proposes to open Great Bay National Wildlife Refuge to migratory game bird (waterfowl) hunting and big game (deer) hunting.

Request for Comments

Department of the Interior policy is, whenever practicable, to afford the public a meaningful opportunity to participate in the rulemaking process. A 60-day comment period is specified in order to facilitate public input. Accordingly, interested persons may submit written comments concerning this proposed rule to the person listed above under the heading **ADDRESSES**. All substantive comments will be reviewed and considered.

Statutory Authority

The National Wildlife Refuge System Administration Act of 1966, as amended (NWRSAA) (16 U.S.C. 668dd), and the Refuge Recreation Act of 1962 (RRA) (16 U.S.C. 460k) govern the administration and public use of national wildlife refuges. Specifically, Section 4(d)(1)(A) of the NWRSAA authorizes the Secretary to permit the use of any areas within the National Wildlife Refuge System (Refuge System) for any purpose, including but not limited to hunting, fishing, public recreation and accommodations, and access, when he determines that such uses are compatible with the purposes for which each refuge was established. The Director of the U.S. Fish and Wildlife Service (Director), administers the Refuge System on behalf of the Secretary. The RRA gives the Secretary additional authority to administer refuge areas within the Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary purposes for which the refuges were established.

Opening Package

In preparation for this opening, the refuge unit has included in its ''openings package'' for Regional review and approval from the Washington Office the following documents: a management plan for recreational hunting; an environmental assessment; a Finding of No Significant Impact (FONSI); a Section 7 statement, pursuant to the Endangered Species Act, that this opening will not affect a listed species or its critical habitat; and refuge-specific regulations to administer the hunting program. From a review of the totality of these documents, The Service has determined that the opening of the Great Bay National Wildlife Refuge to hunting is compatible with the principles of sound wildlife management and will otherwise be in the public interest.

In accordance with the NWRSAA and the RRA, the Service has also determined that this opening for hunting is compatible and consistent with the primary purposes for which the refuge was established. A brief description of the hunting program is as follows:

Great Bay National Wildlife Refuge

Great Bay National Wildlife Refuge was authorized in December, 1991, when an Act of Congress approved the transfer of 1,000 acres of land at Pease Air Force Base in Newington, New Hampshire to the Fish and Wildlife Service. The refuge was established August 11, 1992, with the signing of the transfer document. The refuge was established for the purposes (1) to encourage the natural diversity of plant, fish and wildlife species within the refuge, and to provide for their